1690276

Siemens Medical Solutions USA, Inc. **Ultrasound Division**

ACUSON X300 [™] Diagnostic Ultrasound System 510(k) Submission

510(k) Summary

Sponsor:

Siemens Medical Solutions, Inc.,

Ultrasound Division 1230 Shorebird Way

Mountain View, California 94043

FEB 1 9 2009

Contact Person:

Shelly Pearce

Telephone:

(650) 694-5988

Fax:

(650) 694-5580

Submission Date:

January 6, 2009

Device Name:

ACUSON X300[™] Diagnostic Ultrasound System

SONOVISTA X300 Diagnostic Ultrasound System

ACUSON X300[™] Diagnostic Ultrasound System, premium edition

Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class:

Review Category:

Tier II

Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYN Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

Diagnostic Intravascular Catheter

FR # 870.1200

Product Code 74-DQO

A. Legally Marketed Predicate Devices

The Siemens Acuson X300 ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens Acuson X300 ultrasound system (K080760, K072676, K071036 and K061946) and the following:

- K050240, ACUSON CV70 Cardiovascular System
- K063085, ACUSON Sequoia Ultrasound System
- K071036, Acuson X300 Diagnostic Ultrasound System
- K080760, ACUSON X300[™] Diagnostic Ultrasound System, premiunm edition
- K083149, Arterial Health Package (AHP) software

B. Device Description:

The Acuson X300 has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
 - EN/IEC 60601-1-4
 - EN/IEC 60601-1-6
 - EN/IEC 60601-2-18
 - EN/IEC 60601-2-25
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The Acuson X300 modifications are verified and validated according to the company's design control process.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Siemens Medical Solutions USA, Inc., Ultrasound Group % Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 1 9 2009

Re: K090276

Trade/Device Name: Acuson X300 Diagnostic Ultrasound Systems.

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: February 3, 2009 Received: February 4, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson X300 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

P4-2 Phased Sector Array

CH5-2 Convex Array

VF10-5 Linear Array L9-5 Linear Array

EC9-4 Convex Array

EV9-4 Convex Array

VF13-5 Linear Array P8-4 Phased Sector Array BE 9-4 Convex Array CW2 Continuous Wave CW5 Continuous Wave AcuNav 8F Intracardiac AcuNav 10F Intracardiac V5Ms TEE 4V1c Phased Sector Array VF13-5SP Linear Array C8-5 Tightly Curved Array 8L3 Linear "Regel" 10V4 Phased Array G7F2 Curved Array Mechanical 3D/4D EV9F4 Curved Array Mechanical 3D/4D L13F5 3D/4D Mechanical Wobbler Linear VF8-3 Linear Array P5-1 Phased Array C6-2 Convex Array SoundStar 10F P9-4 Phased Array

n Grines

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean 'that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and reapplicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1600-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

G Janine M. Morris

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

ACUSON X300[™] Diagnostic Ultrasound System 510(k) Submission

Indications for Use Statement

510(k) Number (if known): 1090276

Device Name: Acuson X300 Diagnostic Ultrasound System

Indications For Use:

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name: Intended Use: **ACUSON X300 Diagnostic Ultrasound Systems**

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Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of Op	eratio	n			****		<u> </u>	
Other (Track t Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								uguigi		
	Fetal		Р	Р	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		Р	P [·]	P	P	e.	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)		Р	Ρ	Р.	Р	<u>a</u>	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		Р	þ	Р	P	Ρ	P		BMDC	Note 2,3,4,5,7,8,9,11
Fetal	Laparoscopic Pediatric					1, 1, 1	-		4		
			Р	P	Р	P	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmailOrgan (Note 1)		Р	₽	Р	Р	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		Р	Р	Р	P	P.	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal		Р	Р	P		Р	Р		8MDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal Trans-urethral		P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
								· ·	٠.		
	Trans-esoph. (non-Card.) Musculo-sket.		Р	Р	Р		. Р	P	W71	BMDC	Note 2,3,4,5,7,8,9,11
	(Convent.) Musculo-skel.		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	(Superfic)		Р	Р	Р	P	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
-	Intra -vascular		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	Ρ	P	P	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Adult		P	P	P	.Р.,	. Р	P		BMDC	Note 2,3,4,5,7,8,9,11 <u>,1</u>
Cardiac	Cardiac Pediatric		Р	P	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)		P	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-escahageal (Cardiac)		P _a	Ę,	. ,2	, p	7	ρ	it.	BMDC	Note 23,4,5,7,8,9,11
	Intra-Continue		Þ	Р	р	P	P	. Р.		BMDC*	Note 2,3,4,5,7,8,9,11
B-dit	Other (Specify)		Р	P	Р	P	Р	Ρ		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral Vessel	Peripheral vessel		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11,1
	Other (Specify) on: P = previously cle		Ρ	P	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9,11

For example: breast, testes, thyroid, penis, prostate, etc.

Ensemble tissue harmonic imaging Note 2

Note 3

3D imaging B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

SieClear multi-view spatial compounding Tissue Equalization Technology Note 8

Note 9

Intracardiac Imaging Dynamic TCE AHP Note 10

Note 11 Note 12

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign/Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

KO 90276

510(k) Number (if known):

Device Name:

P4-2 Phased Sector Array Transducer for use with:

Intended Use:

ACUSON X300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of O	peratio	n .						
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic ,	Ophthalmic										· · · · · · · · · · · · · · · · · · ·
	Fetal		Р	Р	Р	Р	Р	Р		8MDC	Note 2,3,4,5,7,8,9,11
	Abdominal		` - В	P	Р	Ρ.	Р	P		BMDC	Note 2,3,5,6,7,8,9,11
	intra-operative (Note 6)		"								
*. •	Intra-operative (Neuro)										
F	Laparoscopic	!	ļ								
Fetal	Pediatric		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)										
	Neonatal Cephalic		Р	Р	Р	Р	. Р	P		BMDC	Note 2,3,4,5,7,8,9,11
1	Adult Cephalic		۹ .	P	P	P	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal							•			
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)						·				
	Musculo-skel. (Convent.)										*.
·	Musculo-skel. (Superfic)										
	Intra-vascular		<u> </u>								
,	Other (Specify)				:						
	Cardiac Adult		Р	Р	Р	Р	Р	Р		BMDC	, Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Pediatric		Р	Р	P	Р	Р.	Р		.∂.BMDC	Note 2,3,4,5,7,8,9,15
	inica-vascular (Carolisc)		. :w			7.				To the same of the	
an gi y And	Trans-esophageal (Cardiac)								7711		
	Intra-cardiac										1
	Other (Specify)										
Peripheral	Peripheral vessel		Р	P	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,1
Vessel	Other (Specify)	1	1	$\overline{}$			1			 	50,710,110,071

N = new indication; P = previously cleared by K080760

Nobel 1	For example: breast, testes, thyrold, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging

K090276

S&W SieScape panoramic imaging Power SieScape panoramic imaging For example: abdominal, vascular Contrast agent imaging SieClear multi-view spatial compounding Note 4 Note 5 Note 6

Note 8 Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging Dynamic TCE Note 11

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(Division Sign-Off)	Concurrence of CDRH, Office of Dev	ice Evaluation (ODE)
Division of Reproductive, Abo	lominal and	•
Radiological Devices	•	\

510(k) Number

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of Op	eratio	n .						
Other { Track1 Only)	Specific (Tracks1l& 3)	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic		٠.,		!						
**	Fetal		Р	Ρ.	Р		Р	Р	.,	BMDC	Note 2,3,4,5;7,8,9,11
1 3 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Abdominal		p	. 10	P) - E	្រំ ខាង។	Р	ar .	BMDC	Note 2,3,4,5,7,8,9,11
•	Intra-operative (Note 6)						,				
	Intra-operative (Neuro)										
	Laparoscopic										:
Fetal	Pediatric		P	P	₽		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)							,			
	Neonatal Cephalic										
	Adult Cephalic									i	
	Trans-rectal						_				
	Trans-vaginal										
	Trans-urethral								<u> </u>		
,	Trans-esoph. (non-Card.)										
•	Musculo-skel. (Convent.)		Р	P	• Р		Ρ	Р		BMDC	Note 2.3.4.5.7.8.9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult		P	P	. Р		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Pediatric		Р	Р	Р		Р	Ρ,		BMDC	Note 2,3,4,5,7,8,9,1
	Intra-vascular (Cardlac) Trans-esophageal	<i>3 ,</i>			เพราะเนียวกานแกล่งร		in ray of the same				
<u>.</u>	(Caidiac)					l,					-
	Other (Specify)			_		1					
Peripheral	Peripheral vessel		Р	Р	P		P	P		. BMDC	Note
Vessel	Other (Specify)	 	1	\vdash	 	·		 	<u> </u>		2,3,4,5,7,8,9,1

Note	1	For example:	breast, testas,	thyrold, penis.	prostate, etc.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

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Note 2 Ensemble tissue harmonic imaging

Note 3

Note 4

³D imaging 8&W SieScape panoramic imaging Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Note 8

Contrast agent imaging
SieClear multi-view spatial compounding
Tissue Equalization Technology
Intracardiac imaging
Oynamic TCE

Note 9

Note 10

Note 11.

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Note 2 Note 3

510(k) Number _

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mode	e of Op	eratio	n						
Other (Track1 Only)	Specific (Tracks1l& 3)	Α	В	М	PWD	ĊWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic			-							
	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		Р	P	ρ	in the second	Þ	р	, ,	BMDC.	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)	·									
	Intra-operative (Neuro)									.=	
l	Laparoscopic										1
Fetal	Pediatric		р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)	.	Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic	·	Р	P	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Aduit Cephalic										
	Trans-rectal							,			
	Trans-vaginal							-	}	-	*** -
	Trans-urethral										
	Trans-esoph. (non-Card.)						j.			,	•
	Musculo-skel. (Convent.)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic) Intra-vascular		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other	_	<u> </u>								
	(Specify)			7	1					: :	
	Cardiac Adult										
Cardiac	Cardiac Pediatric			<u> </u>					<u> </u>		Note 12
1	latra-vascular (Cardiau)	 				1			1 7 7		1333.12
	Trans-scopiespeal (Cardiac) -	A						T.A.			
	Intra-cardiac		ļ			Ļ				-	
	Other (Specify)										
Peripheral	Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11,12
Vessel	Other (Specify)	ared by	1 ~								

Ensemble tissue harmonic imaging 3D imaging B&W SieScape panoramic imaging Power SieScape panoramic imaging For example: abdominal, vascular Note 4 Note 5 Contrast agent imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 8 Note 9 Note 10 Note 11 Intracardiac imaging Dynamic TCE Note 12 (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) (Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices

For example: breast, testes, thyroid, penis, prostate, etc.

510(k) Number (if known):

Device Name:

L9-5 Linear Array Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of O	peratio	п		·—	,		<u> </u>	
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М.	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdomina		Р	P.	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)							·			2,3,4,3,1,0,3,11
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric		Ρ	Р	Р		Ρ.	·P		BMDC	Note 2,3,4,5,7,8,9,11
lmaging & Other	SmallOrgan (Note 1)		Р	Р	Ρ		Р	P.		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		Р	Р	Р		P	P		BMDC	Note
	Adult Cephalic										2,3,4,5,7,8,9,11
	Trans-rectal										
	Trans-vaginal						-				
	Trans-urethral										
	Trans-esoph. (non-Card.)	·					-				
	Musculo-skel. (Convent.)		Ð	Ρ	Р	1	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)	1	P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										2,3,4,3,1,0,9,11
	Other (Specify)				_				,		
	Cardiac Adult										
Cardiac	Cardiac Pediatric										Note 12
	Intra-vascular (Certiac)				· · · · · · · · · · · · · · · · · · ·	-			a de la companya de l		
	(Cartino)	****									
	Intra-Cardaic								.		
	Other (Specify)										P
Peripheral	Peripheral vessel	,	Р	ρ	Р		P	Р	-	BMDC	Note 2,3,4,5,7,8,9,11,12
Vessel	Other (Specify) ion; P = previously clea						-				=,0,7,0,7,0,0,1 L1Z

For example: breast, testes, thyroid, penis, prostate, etc.
Ensemble tissue harmonic imaging
3D imaging
B&W SieScape panoramic imaging
Power SieScape panoramic imaging
For example, abdominal, vascular Note 1

Note 2 Note 3

Note 4

Note 5

Note 6

Note 7

Contrast agent imaging SieCtear multi-view spatial compounding Tissue Equalization Technology Note 8

Note 9

Intracardiac imaging Dynamic TCE AHP Note 10

Note 11

Note 12

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

KO90276

510(k) Number (if known):

Device Name:

EC9-4 Convex Array Transducer for use with:

Intended Use:

ACUSON X300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mod	e of Op	eratio	n	•					
Other (Track1 Only)	Specific (Tracks1l& 3)	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic									•	
	Fetal	;	P	Ρ	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal					41% 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
	Intra-operative (Note 6)							·			
	Intra-operative (Neuro)										
	Laparoscopic										
Fetæl	Pediatric										
lmaging & Other	SmallOrgan (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	Р	Ρ		₽	Р		BMDC	Note 2,3,4,5,7,8,9,11
Ac	Adult Cephalic										2/3/1/3/1/3/1/1
	Trans-rectal		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular			<u> </u>							
	Other (Specify)										
	Cardiac Adult										
Cardiac	Cardiac Pediatrio			- 1] :	STREET, STORY				10000
	intra-vascular (Cardisc)						•	4	Andreas de la company de l La company de la company de		Part of the second seco
* + ***	Trans-esophageal (Cardiac)										
	Intra-Cardiac				,						
	Other (Specify)		T					1			
Peripheral	Peripheral vessel										
Vessel	Other (Specify)	Ī	Ι		1 -		<u> </u>		-	-	

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 8&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac Imaging Note 11 Dynamic TCE

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(Division Sign-Off)	0	Prescription Use (Per 21 CFR 801.109)	35 2,
Division of Reproductive	. Abdominal and	•	•

Division of Reproductive, Abdomin Radiological Devices

510(k) Number .

510(k) Number (if known):

Device Name:

Intended Use:

EV9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mod	e of O	peratio	n						
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD.	Calar Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	P	D.		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal			## ^{(*}	-14			2.4		* . v 1	
	Intra-operative (Note 6)									·	
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pedlatric										
Imaging & Other	SmallOrgan (Note 1)		Р	P	Р		Р	Р		вмос	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		Ρ	Р	Р	-	P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic						·				
	Trans-rectal		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		Р	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral		ļ								
	Trans-esoph. (non-Card.)			·			, , , , , , , , , , , , , , , , , , ,				
	Musculo-skel. (Convent.)									<u>_</u>	
	Musculo-skel. (Superfic)										:
	intra-vascular	<u> </u>	<u> </u>								
	Other (Specify)							· -			, , , , , , , , , , , , , , , , , , , ,
	Cardiac Adult										
Cardiac	Cardiac Pediatric			•		1 1723				3 A	WE WE WAY
	liste-vascular (Cardisc)	1	1				<u> </u>		ii -	-	,
	Trans-esophageal (Cardiac)	***	144								
	Intra-Cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel				7.		,]	
Vessel	Other (Specify)		T	П		T T	1		<u> </u>	 	

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic Imaging
Note 5	Power SieScape panoramic Imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SleCtear multi-view spatial compounding
Note 9	Tissue Equalization Technology
Note 10	Intracardiac imaging
Note 11	Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) (Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number ___ 1090276

510(k) Number (if known):

Device Name:

VF13-5 Linear Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ition	Mode	e of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		Р	P	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		Р	Р	Р		P	P		BMDC	* Note * 2,3,4,5,7,8,9,11
	intra-operative (e stchi)										3
	intra-operative (Neuro)										
	Laparoscopic		<u> </u>								
Fetal	Pediatric		Р	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
imaging & Other	SmallOrgan (Note 1)		Р	Р	Р		ρ	Þ		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic						•			· · · · · · · · · · · · · · · · · · ·	2,0,1,0,1,0,0,1
	Trans-rectal		İ								
	Trans-vaginal								,		
•	Trans-urethral										
,	Trans-esoph. (non-Card.)							ļ			
	Musculo-skel. (Convent.)		Р	Р	Р	-	<u>.</u>	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		Р	Р	₽		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular	<u> </u>									
	Other (Specify)										
	Cardiac Adult		<u> </u>								Note 12
Cardiac	Cardiac Pediatric		<u> </u>	ļ							
	Intra-vascular (Cardiac)										
	Trais asophageal (Cardias)			N 1993	Netron second	Tables MPS (STREET	**				,
-	inira-cardiac	1				the type (game or the same				>	
	Other (Specify)			4					İ		
Peripheral	Peripheral vessel	1	P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11,1
Vessel	Other (Specify)	1	1				<u> </u>				

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

Note 11 Dynamic TCE

Note 12 AHP

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTH Concurrence of CDRH, Office of Device Evaluation (1 Prescription Use (Per 21 CFR 801.109)	
(Division Sign-Off)	
Division of Reproductive, Abdominal and	•

Radiological Devices

510(k) Number <u>Koge 76</u>

510(k) Number (if known):

Device Name:

P8-4 Phased Sector Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	of Op	peratio	n į						
Other (Track1 Only)	Specific (Tracks1l& 3)	А	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic			·							
	Fetal		Р	P	Р	Р	Р	Р .		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		. Р	o	P	p	c.	P		BMDC	Note 2,3,5,6,7,8,9,11
:	Intra-operative (Note 6)		• .	•••		. •					
	Intra-operative (Neuro)							-			
	Laparoscopic	.					`				
Fetal	Pediatric	1	Р	Р	P	Р	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)										,
	Neonatal Cephalic		Р	Р	P	Р	P	ρ		BMDC	Note 2,3,4,5,7,8,9,11
•	Adult Cephalic					,					
	Trans-rectal									-	
	Trans-vaginal	<u> </u>									
	Trans-urethral Trans-esoph.	ļ		<u> </u>	ļ						
	(non-Card.)				l .						
	Musculo-skel. (Convent.)		Ъ	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-akel. (Superfic)										·
	Intra-vascular Other	<u>. </u>		<u> </u>					ļ		
	(Specify)]				•	:		·
	Cardiac Adult		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Pediatric		P	. Р	Р	P	. Р	Р		BMDC	Note 2,3,4,5,7,8.9,11
	Intra-vesculor (Cardien)									2.5	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	Trans-ezophagean (Cardiac)	1.76									7 - (A) - (A
	Intra-cardiac	<u> </u>		<u> </u>	<u> </u>	ļ				,	
	Other (Specify)	₩									
Peripheral	Peripheral vessel		P	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)						I		1		

N = new indication; P = previously cleared by K080760

Note 1	For example: breast,	testes, thyrold,	penis,	prostate, etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3

³D imaging B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging For example: abdominal, vascular Note 5

Nate 6 Note 7

Contrast agent Imaging
SieClear multi-view spatial compounding
Tissue Equalization Technology
Intracardiac imaging
Dynamic TCE Note 8

Note 9

Note 10

Note 11

510(k) Number (if known):

Device Name:

BE 9-4 Convex Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation											
Other (Track1 Only)	Specific (Tracks11& 3)	A	8	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic												
	Fetal		P	P	P		P	Р		BMDC	Note 2,3,4,5,7,8,9		
1.27	Abdominal -	, and											
·	Intra-operative (Note 6)												
· [Intra-operative (Neuro)										<u> </u>		
[Laparoscopic						-						
Fetal	Pediatric												
lmaging & Other	SmallOrgan (Note 1)		Р	Р	Ρ		P	P		BMDC	Note 2,3,4,5,7,8,9		
	Neonatal Caphalic		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9		
i	Adult Cephalic												
	Trans-rectal		Р	Р	P	·	Р	Р		BMDC	Note 2,3,4,5,7,8,5		
	Trans-vaginal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9		
	Trans-urethral												
. [Trans-esoph. (non-Card.)												
1	Musculo-skel. (Convent.)	1					:						
	Musculo-skel. (Superfic)				<u></u>		-						
	Intra-vescular										,		
	Other (Specify)												
	Cardiac Adult												
Cardiac	Cardiac Pediatric					1					,		
	Intra-vascular (Clarding)							1.5	es (2.3)	3.30			
_	Trans-esophageat (Cardiac)- '>				31					4.4	er sjokket ok		
	lintra-cardiac			1	*5					* ****			
	Other (Specify)												
Peripheral	Peripheral vessel												
Vessel	Other (Specify)		-	1									

N = new indication; P = previously cleared by K080760

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Nate 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SieClear multi-view spatial compounding
Note 9	Tissue Equalization Technology
Note 10	Intracardiac imaging
Note 11	Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

(Division Sign-Off)

510(k) Number <u>K090276</u>

510(k) Number (if known):

Device Name:

CW2 Continuous Wave Doppler Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of Q	peratio	n.						
Other (Track1 Only)	Specific (Tracks1l& 3)	А	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other . (Specify)
Ophthalmic	Ophthalmic										
.*	Fetal					Ρ.		·			
	Abdominal					Р					
	Intra-operative (Note 6)			.;.		P ?				٠.	
	Intra-operative (Neuro)										<u> </u>
-	Laparoscopic					ļ					
Fetal	Pediatric					Р					
lmaging & Other	SmallOrgan (Note 1)					P		-			
	Neonatal Cephalic					P		·			
	Adult Cephalic					P			ļ ———		
	Trans-rectal		 	 		 			 		
	Trans-vaginal		\vdash								
	Trans-urethral				·						
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					₽					
	Musculo-skel. (Superfic)				32		1				
	Intra-vascular Other										
	(Specify)										•
	Cardiac Adult					Р					
Cardiac	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)							,	-		
	Trans-esophageal (Cardiac)										
3.	Intra-cardiac	.55					CONTRACTOR	1	4. 22 - 1 (party 2) m		ing ign
era e e e e	Other (Specify)		-C#-			NAME AND POST OF THE OWNER.			}	T	ra and a product of the second
Peripheral:	Peripheral vessal					P	200		an second		
Vessel	Other (Specify)		I						 		

N = new indication; P = previously cleared by K080760

Note	1	For example: oreast,	taptae th	umid nonic	nmatata ata
	•	A OL OVERHÖLEN DIGEST	wawa, u i	yrutu, portis,	piusiale, sic.

Note 11 Dynamic TCE

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(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K090276

Note 2 Note 3 Note 4 Ensemble tissue harmonic imaging

B&W SleScape panoramic imaging Power SieScape panoramic imaging For example: abdominal, vascular Note 5

Note 6 Note 7

Contrast agent Imaging
SieClear multi-view spatial compounding
Tissue Equalization Technology Note 8

Note 9

Note 10 Intracardiac imaging

510(k) Number (if known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ation	Mod	e of Op	peratio:	n					,	
Other (Track1 Only)	Specific (Tracks1i& 3)	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal			,		P					
	Abdominal					Р					
	Intra-operative (Note 6)				•	P :		•		,	
	Intra-operative (Neuro)			`							
	Laparoscopic						·				
Fetal	Pediatric					Р					
lmaging & Other	SmallOrgan (Note 1)				 · <u></u>	P					<u> </u>
	Neonatal Cephalic					P					
	Adult Cephalic					Р			-:		
	Trans-rectal										
	Trans-vaginal								,		
	Trans-urethral							l			
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
-	Musculo-skel. (Superfic)					.,	, .				
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult					Р					
Cardiac	Cardiac Pediatric					Р					
	intra-vascular (Cardiac)	<u> </u>									et ø
. M	Trans-esophageal (Cardiac)				erre aprillage e sancia de					~ "	
	Intra-Cardisc	: .	·		6, Di- 721931/C 000			•			
	Other (Specify)		1		territoria de la constitución de		4				
Peripheral :	Peripheral vessel		<i>35</i> :		THE STREET IN CO.	P		The second second			
Vessel -	Other (Specify)	1	F				· · ·			-	

Note 1	For example: breast, testes, thyrold, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic Imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SleClear multi-view spatial compounding
Note 9	Tissue Equalization Technology
Note 10	Intracardiac Imagino

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

Dynamic TCE

510(k) Number (if known):

Device Name:

AcuNav 8F Intracardiac Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	e of O	peratio	n.						
Other (Track1 Only)	Specific (Tracks1l& 3)	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal					-		·			
eri Tri	Abdominal					2			٠,		
	Intra-operative (Note 6)										es and a second
	Intra-operative (Neuro)										
	Laparoscopic								-		
Fetal	Pediatric		P	Р	Р	Р	Р	Ь		BMDC	Note 2,3,7,8,9,10,11
Imaging & Other	SmallOrgan (Note 1)										-
-	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal							 			
	Trans-vaginal					 					
	Trans-urethral										
	Trans-esoph. (non-Card.)				· · · · · · · · · · · · · · · · · · ·						
	Musculo-skel. (Convent.)									*	
	Musculo-skel. (Superfic)										
	Intra-vascular		P	Р	P	P	Р	Р		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
	Cardiac Adult		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8,9,10,11
Cardlac	Cardiac Pediatric		Ρ	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8.9, (0,13).
	Intra-vascular (Cardiac)		£	,: ' i	р	Ė	. 2	A		ВМБС	Note, 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)				1			ana opti je u	ξ(*		-143, 444, 444
	Intra-cardiac		P	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										£,0,7,0,0, (U, 1)
Peripheral	Peripheral vessel				-				· · · · · · · · · · · · · · · · · · ·		
Vessel	Other (Specify)					<u> </u>	 				<u> </u>

For example: breast, testes, thyroid, pents, prostate, etc. Ensemble tissue harmonic imaging 3D imaging 8&W SleScape panoramic imaging Power SieScape panoramic imaging Note 2 Note 3 Note 4 Note 5 Note 6

For example: abdominat, vascular
Contrast agent imaging
SieClear multi-view spatial compounding
Tissue Equalization Technology Note 7

Intracardiac imaging
Dynamic TCE Note 10

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Proscription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

510(k) Number (if known):

Device Name:

AcuNav 10F Intracardiac Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Other		Mode	of Op	eratlo	n						
Other (Track1 Only)	Specific (Tracks1l& 3)	Α	8	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Cambined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic						,				
	Fetal		·								
	Abdominal										
	intra-operative (Note 6)			•			- * *				
	Intra-operative (Neuro)						,				
	Laparoscopic	<u> </u>								·	
Fetal	Pediatric		Р	Р	P	Р	Р	P		BMDC	Note 2,3,7,8,9,10,11
lmaging & Other	SmallOrgan (Note 1)										2(0)/(0)0/(0)
	Neonatal Caphalic								_		
	Adult Cephalic	!									
	Trans-rectal				· · · · · · · · · · · · · · · · · · ·						. **
	Trans-vaginal					``		·			
	Trans-urethral									-	
	Traris-esoph. (non-Card.)		·								
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)					· ·	,				
	Intra-vascutar		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										2,0,1,0,5,10,11
	Cardiac Adult		P	P	P·	Р	P	P		BMDC	Note 2,3,7,8,9,10,11
Cardiac	Cardiac Pediatric		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Caxtiso)		Р	P	Р	Р	P	Р		BMDC	Note 23.79.9.19.11
	Trans-esophagnai (Cardiar)		is Dan kans								
	Intra-cardiac		Р	Р	Р	P	Р	Р	7.90	Вмос	Note 2,3,7,8,9,10,11
	Other (Specify)	1	<u> </u>			 	· -			-	2,0,1,0,5,10,11
Peripheral	Peripheral vessel								† · · · · · ·	i 	
Vessel	Other (Specify)	T		1				1	1	1	

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(Division Sign-Off)	UPR 801.1	(03)
Division of Reproductive, Abdominal and		

Radiological Devices

510(k) Number <u>K090276</u>

510(k) Number (if known):

Device Name:

V5Ms TEE Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	cation	Mod	e of O	peratio	n						· · · · · · · · · · · · · · · · · · ·
Other (Track1 Only)	Specific (Tracks1i& 3)	Α	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthaimic	Ophthalmic										
	Fetal								·		
·	Abdominal										
	Intra-operative (Note 6)						֔		#	, 1-	
	Intra-operative (Neuro)			-	· ·						·
	Laparoscopic										
Fetal	Pediatric					ζ.					i
lmaging & Other	SmallOrgan (Note 1)									· · · · · · · · · · · · · · · · · · ·	
	Neonatal Cephalic		 						L. <u>_</u>		
	Adult Cephalic	\vdash	 								
•	Trans-rectal	_	 	 		 	 				
	Trans-vaginal	1						·	<u> </u>		
	Trans-urethral			 			<u> </u>				
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular	<u> </u>	<u> </u>		,						
	Other (Specify)										
	Cardiac Adult		Ρ	Ρ	P	Р	Р	Р	[BMDC	Note 2,3,7,8,9,11
Cardiac	Cardiac Pediatric		Р	Р	Р	Р	Ρ.	P		BMDC	Note 2,3,7,8,9,11
	Intra-vascular (Cardiac)							,			
4.	Trans-esophageal (Cardiac)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,11
	kitte cardige			-		Later by trans transaction	المساد المساحدة				*** *** * **** **** **** **** *** ***
.i	_Otter (Specify)				174477	i we	<u> </u>		-		
Peripheral	Peripheral vessel			4.	,	· H.	20.00				· flags and Section 1
Vessel	Other (Specify)		K0807				,		i		

Note 1 Note 2 For example: breast, testes, thyroid, penis, prostate, etc. Ensemble tissue harmonic imaging 3D imaging 8&W SieScape panoramic imaging Power SieScape panoramic imaging Note 3 Note 6 For example: abdominal, vascular Note 7 Contrast agent imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 8 Note 9 Note 10 Note 11

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(Division Sign-Off)

Division of Reproductive, Abdominal and

intracerdiac imaging Dynamic TCE

Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

4V1c Phased Sector Array Transducer for use with:

Intended Use:

ACUSON X300 Diagnostic Ultrasound Systems
Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mode of Operation										
Other (Track1 Only)	Specific (Tracks1I& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic			Ĺ.						,		
	Fetal		P	Р	Р	Р	P	P		BMDC	Note 2,3,4,5,7,8,9	
	Abdominal		P	Р	Р	Р	P	. P		BMDC	Note 2,3,5,6,7,8,9	
	Intra-operative (Note 6)			,		100			-		,	
	Intra-operative (Neuro)						-					
	Laparoscopic											
Fetal	Pedlatric		Р	Р	Р	Р	Р	. Р		вмос	Note 2,3,4,5,7,8,9	
lmaging & Other	SmallOrgan (Note 1)											
	Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9	
	Adult Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,	
	Trans-rectal											
i	Trans-vaginal						1			1		
	Trans-urethral										1	
	Trans-esoph. (non-Card.)		-						-			
	Musculo-skel.											
	(Convent.) Musculo-skel.			 		-	 					
	(Superfic)			1	İ							
	Intra-vascular			1						1	T	
	Other (Specify)											
	Cardiac Adult	1.	P	Р	P	P	P	Р		BMDC	Note 2,3,4,5,7,8,	
Cardiac	Cardiac Pediatric		Ρ	P	Р	Р	Р	P.		BMDC	Note 2,3,4,5,7,8,	
	intra-vascular (Cardiac)											
	Trans-esophageal (Carciac)		e systemetri	ļ			+540			200		
1.0	inira-caidise	1	استنيا شد (۱۳۷۰ - ۱	į			with a school of comments of country			Ţ		
	Other (Specify)	3		ì								
Peripheral	Peripheral vessel		Р	₽	Р	Р	Р	. Р		BMDC	Note 2,3,4,5,7,8	
Vessel	Other (Specify)	1		1		T			Ï			

For example: breast, testes, thyroid, penis, prostate, etc.
Ensemble tissue harmonic imaging
3D imaging
B&W SieScape panoramic imaging
Power SieScape panoramic imaging
For example: addominat, vascular Note 1 Note 2 Note 3 Note 4 Note 5 Note 6 Note 7 Contrast agent imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 9 Note 10 Note 11 Intracardiac imaging

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Division Sign-Off)	

Division of Reproductive, Abdominal and

Dynamic TCE

Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

VF13-5SP Linear Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluld flow analysis of the human body as follows:

Clinical Applica	tion	Made	e of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	A	B	М	PWD	CWD	Color Doppler	Amplitude Doppler	Calar Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	ľ									
	Fetal										
	Abdominal		,								
	Intra-operative (Note 6)		P	Ρ	b.		Ĵ·β	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9.11
	Laparoscopic										
Fetal	Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9.11
Imaging & Other	SmallOrgan (Note 1)		P	Ρ	Р		P	P		BMĐC	Note 2,3,4,5,7,8,9.11
	Neonatal Cephalic		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9.11
	Adult Cephalic			ļ							
	Trans-rectal							,			
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)				·						
·	Musculo-skel. (Convent.)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9.11
	Musculo-skel. (Superfic)		P	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9.11
	Intra-vascular						<u> </u>				
	Other (Specify)										
	Cardiac Adult										Note 12
Cardiac	Cardiac Pediatric							<u> </u>			
	intra-vascular (Cardiac)										
	Trans-esophageal (Carrliac)		*****************	PROFESSION AND ADMINISTRA							
	Intra-cardiac	2010.70	_			Large water sector —		1		L	
100	Other (Specify)										
Peripheral	Peripheral vessel		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,9,:11 2
Vessel	Other (Specify)							 	· · · · · · · · · · · · · · · · · · ·	-	
N = new indicat	ion; P = previously cle	المحمد	. Knoc	100		<u> </u>		<u> </u>		<u> </u>	

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 B&W SieScape panoramic imaging

Note 5 Por example: abdominal, vascular

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Tissue Equalization Technology

Note 10 Intracardiac imaging

Note 11 Dynamic TCE

Note 12 AHP

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(Division Sign-Off)		Prescription Use (Per 21 CFR 801.109))
Division of Reproductive, Ab	dominal and	•	•

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

16090276

510(k) Number (if known):

Device Name:

C8-5 Tightly Curved Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	of Op	eration							
Other (Track1 Only)	Specific (Tracks1I& 3)	A.	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										·
	Fetai		Ρ	P	P.		Р	Р		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		. Р	Р	Р		P	ь		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note:6)	- i - i - i		manuta							
	Intra-operative (Neuro)										
	Laparoscopic							-			
-etal	Pediatric		Ρ	Р	, P		Р	Р		BMDC	Note 2,3,4,5,7,8,
maging & Other	SmaliOrgan (Note 1)		Ρ	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8
	Neonatal Cephalic		P	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,
	Adult Cephalic		Р	Р	Р	i	Р	Р		BMDC	Note 2,3,4,5,7,8
	Trans-rectal						-		·		11010 2,00,1,00,1,0
	Trans-vaginal									 	
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		Р	P	P		P	Р		BMDC	Note 2,3,4,5,7,8
	Musculo-skel. (Superfic)		₽	Р	Р	<u> </u>	P	P		BMDC	Note 2,3,4,5,7,8
•	Intra-vascular										
	Other (Specify)				`		"				
	Cardiac Adult		Р	Ρ	P		Р	Р		BMDC	Note 2,3,4,5,7,8
Cardiac	Cardiac Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
	Intra-vascular (Cardiac)										
	Trans-esophageal Translac)		<i>,</i> , ,		t raine in the aritim	Same parables are and		San Lauran et a		THE SECOND STREET, SECOND SECO	C) N/P / / TOO - 1 - C - TO - 1 - C - C - C - C - C - C - C - C - C
	Intra-cardiac	14.92			Himoras — des di — est	·	and the second			1	
	Other (Specify)					•			44)	
Peripheral	Peripheral vessel		₽	Þ	Р		P	P	,	BMDC	Note 2,3,4,5,7,6

ndication; P = previously cleared by K080760

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic Imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SleClear multi-view spatial compounding
Note 9	Tissue Equalization Technology
Note 10	Intracardiac Imaging
Note 11	Dunamic TCF

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

8L3 Linear "Regel" Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ition	Mode	e of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic									ı	
	Fetal		P	Ρ·	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		Р	P	P	1	. Р	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operativo (Note 6)										
	Intra-operative (Neuro)									<u>.</u>	
	Laparoscopic								<u> </u>		
Fetal	Pediatric	1	Р	Ρ	Р	1	P	'P		BMDC	Note 2,3,4,5,7,8,9
Imaging & Other	SmallOrgan (Note 1)		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic					<u> </u>		 	† <u>-</u>		
İ	Trans-rectal										
	Trans-vaginal						· <u>-</u>				
	Trans-urethral										,
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		₽	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,
:	Musculo-skei. (Superfic)		₽	p.	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,
	Intra-vascular										
	Other (Specify)				,						
	Cardiac Adult	<u> </u>									Note 12
Cardiac	Cardiac Pediatric										
•	Intra-vascular (Cardiac)										
	Trans-esophageal (Cordiac)	1 20				,					
	intra-cards				T.		5.9			-	
	Other (Specify) *				The second second		1 /460-F	· · · · · · · · · · · · · · · · · · ·			1
Peripheral	Peripheral vessel		Р	P	Р		P	Р		BMDC	· Note
Vessel	Other (Specify)	1						 	 		2,3,4,5,7,8,9,12

cation; P = previously cleared by K080760

diction; P = previously cleared by K080/60
For example: breast, testes, thyroid, penis, prostate, etc.
Ensemble tissue harmonic imaging
3D imaging
B&W SieScape panoramic imaging
Power SieScape panoramic imaging
For example: abdominal, vascular Note 1 Note 2

Note 3 Note 4

Note 5

Note 6 Contrast agent imaging Note 7

SieClear multi-view spatial compounding Tissue Equalization Technology Note 8

Note 9

Note 10 Intracardiac imaging

Dynamic TCE AHP Note 11

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

KO 90276 510(k) Number

510(k) Number (if known):

Device Name:

10V4 Phased Array Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Optithalmic Optitalmic Optithalmic Optithalmic Optithalmic Optithalmic Optitalmic Opt	Clinical Applica	ation	Mode	e of Op	eration							
Fetal	(Track1		Α	В	М	PWD	CWD			Velocity		Other (Specify)
Abdominal P P P P P P BMOC Note 2,3,4,5, Intra-operative (Note 6) Intra-operative (Neuro) (Neuro) Laparoscopic Pediatric P P P P P P P P BMDC Note 2,3,4,5, Imaging & SmallCrigan (Note 1) Neonatal Cephalic P P P P P P P P BMDC Note 2,3,4,5, Adult Cephalic Trans-rectal Trans-rectal Trans-vaginal Trans-asoph. (non-Card.) Musculo-sket. (Convent.) P P P P P P P P BMDC Note 2,3,4,5, (Superfic) Intra-vascular Other Other Other Cardiac Pediatric P P P P P P P P P BMDC Note 2,3,4,5, Trans-suphageal Cardiac Pediatric P P P P P P P P P BMDC Note 2,3,4,5, Trans-rectal P P P P P P P P P P BMDC Note 2,3,4,5, Cardiac Pediatric P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P P P P BMDC Note 2,3,4,5, Trans-resular Cardiac P P P P P P P P P P P P P P P P P P P	Ophthalmic	Ophthalmic							****			
Abdominal		Fetal		Р	Р	P	Р	Р	Ρ		BMDC .	Note 2 3 4 5 7 8
Intra-operative (Note 6)		Abdominal		·P	Ρ.	Р	, p	P	μ		 	
Neuro	Asia i wa					<u> </u>	<u> </u>					1400 2,3,4,0,1,0,
Petal Pediatric P P P P P P P P P P P P P P P P P P									· · ·			
Imaging & Other SmallOrgan (Note 1) Note 2,3,4,5,		Laparoscopic								 -		
SmallOrgan (Note 1)	Fetal	Pediatric		Р	Р	P	P	Р	ρ		BMDC	Note 3 2 4 5 7 0 1
Adult Cephalic Trans-rectal Trans-vaginal Trans-urethrat Trans-apoph. (non-Card.) Musculo-sket. (Corwent.) Intra-vascular Other (Specify) Cardiac Adult Cardiac P P P P P P P P P P P P P P P P P P P									·	- "	DIVIDO	NOB 2,3,4,3,7,0,
Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-soph. (non-Card.) Musculo-skel. (Corvent.) Musculo-skel. (Superfic) Intra-vascular Other (Specify) Cardiac Adult P P P P P P P P P BMDC Note 2,3,4,5, Cardiac Pediatric P P P P P P P P BMDC Note 2,3,4,5, Mirro-cardiac Trans-sopphageal Cardiac Pediatric Intra-vascular (Cardiac) Trans-sopphageal Cardiac Trans-sopphageal		Neonatal Cephalic		Р	Р	Р	Р	P	Р		RMDC	Note 2 2 4 5 7 9
Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-sket. (Corvent.) Musculo-sket. (Superfic) Intra-vascular Other (Specify) Cardiac Cardiac Adult PPPPPPPPPPPPPPBBMDC Note 2,3,4,5, Cardiac Pediatric PPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPP		Adult Cephalic									DNIDC	140(6 2,3,4,3,7,0,
Trans-urethral		Trans-rectal										
Trans-esoph. (non-Card.)		Trans-vaginal				· · · · · · · · · · · · · · · · · · ·					<u> </u>	
Trans-esoph. (non-Card.) Musculo-skel. (Corvent.) Musculo-skel. (Superfic) Intra-vascular Offier (Specify) Cardiac Adult P P P P P P P P P B BMDC Note 2,3,4,5, Cardiac Pediatric P P P P P P P P P B BMDC Note 2,3,4,5, Intra-vascular (Cardiac) Trans-susphageal Cardiac Other (Specify) Peripheral Peripheral Peripheral Peripheral Parpheral vessel P P P P P P P P P P P P P P P P P P P		Trans-urethral				·						
Corwent P P P P P P P P P P P P P P P P P P		(non-Card.)										
(Superfic) Intra-vascular Other (Specify) Cardiac Adult P P P P P P P P P P BMDC Note 2,3,4,5,		(Convent)		Р	Р	Р	Р	Р	Р	-	BMDC	Note 2,3,4,5,7,8,
Other (Specify) Cardiac Adult PPPPPPPPPPBMDC Note 2,3,4,5, Cardiac Pediatric PPPPPPPPPPBMDC Note 2,3,4,5, (Cardiac) Intra-vascular (Cardiac) (Cardiac) Trans-suchangeal Equipment Cardiac Other (Specify) Peripheral Peripheral vessel PPPPPPPPPPPPPPPPBMDC Note 2,3,4,5, Cardiac PPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPP		(Superfic)							-			
(Specify) Cardiac Adult PPPPPPPPPPPBMDC Note 2,3,4,5, Cardiac Pediatric PPPPPPPPPPPPBMDC Note 2,3,4,5, Cardiac Pediatric PPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPPP												
Cardiac Cardiac Pediatric P P P P P P P P BMDC Note 2,3,4,5, Intra-vascular (Cardiac) Trans-acachageal Cardiac Trans-acachageal Cardiac Trans-acachageal Cardiac Trans-acachageal Cardiac Trans-acachageal Peripheral Peripheral vessel P P P P P P P BMDC Note 2,3,4,5, Intra-vascular (Cardiac)	····	(Specify)										· · · · · · · · · · · · · · · · · · ·
Cardiac Cardiac Pediatric P P P P P P P P BMDC Note 2,3,4,5, Intra-vascular (Cardiac) Trans-susciplageal Cardiac Trans-susciplageal Cardiac Other (Specify) Peripheral Peripheral vessel P P P P P P P BMDC Note 2,3,4,5, Intra-vascular (Cardiac)							P	P	P		BMDC	Note 2,3,4,5,7,8,
Intra-vascular (Cardiac) Trans-samhageal Equiring Intra-cardiac Other (Specify) Peripheral Peripheral vessel P P P P P P P BMDC Note 2.3.4.5	Cardiac			Р	Р	P	P	P	Р		BMDC	Note 2,3,4,5,7,8,
Peripheral vessel P P P P P P BMDC Note 2.3.4.5	. 1	(Cardiac)		.t.ar-								
Other (Specify) Peripheral Peripheral vessel P P P P P P P BMDC Note 2.3.4.5		L'Cardisc			,	***************************************	principle square or other decomposition					2
Peripheral Peripheral vessel PPPPPPPPPBMDC Note 2.3.4.5		C174.00A			/- i	4 4 7 4 E aft 10 1 a m p						the same of
MUC I Note 2.3.4.5	Peripheral			. p i	۱ و	Р	В	В			21/22	
Vessel Other (Specify)	Vessel	Other (Specify)		 -+		F		<u> </u>	Ρ		BMDC	Note 2,3,4,5,7,8,

Note 1	For	example:	breast,	testes.	thyroid, penis,	prostate, etc.

Note 11

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) (Division Sign-Off) Division of Reproductive, Abdominal and Radiological Devices 510(k) Number

Ensemble tissue harmonic imaging

Ensemble tissue narmonic imaging 3D imaging B&W SieScape panoramic imaging Power SieScape panoramic imaging For example: abdominal, vascular Contrast agent imaging SieClear mutit-view spatial compounding Tissue Equalization Technology Intracardian imaging Note 3 Note 4 Note 5 Note 6 Note 7

Note 8

Note 9

Intracardiac imaging Dynamic TCE Note 10

510(k) Number (if known):

Device Name:

C7F2 Curved Array Mechanical 3D/4D Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion	Mode of Operation										
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic				-						· · · · · · · · · · · · · · · · · · ·	
	Fetal		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11	
	Abdomlnal		Р	Р	, P <		۶.	P		BMDC	Note 2,3,4,5,7,8,9,11	
	Intra-operative (Note 6)				,							
	Intra-operative (Neuro)										i	
	Laparoscopic				·							
Fetal	Pediatric		P	Р	Р		Р.	P		BMDC	Note 2,3,4,5,7,8,9,11	
fmaging & Other	SmallOrgan (Note 1)											
	Neonatal Caphalic	i										
	Adult Cephalic			<u> </u>				 			 -	
i	Trans-rectal							1				
İ	Trans-veginal											
	Trans-urethral							l			•	
	Trans-esoph. (non-Card.)						;			-		
·	Musculo-skel. (Convent.)		Р	Р	Р		Р	Р		BMD¢	Note 2,3,4,5,7,8,9,11	
	Musculo-skel. (Superfic)											
	Intra-vascular									,		
	Other (Specify)											
	Cardiac Adult		Р	P	Р		Р	• р.		BMDC	Note 2,3,4,5,7,8,9,11	
Cardiac ,	Cerdisc Pediatric		P	β	ŕ		r .	P		BWIDC.	Note 2,3,45,7,8,9,11	
A. 19	intro-vascular (Cardiac)]				T T		- 4.		AND THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS NAMED IN COLUMN TWO IS	
<i>i i i i i i i i i i i i i i i i i i i </i>	Trans-esophageal (Cardiac)		-			-				₩ 3		
	Intra-cardiac	 -		 	· · ·	ļ	 	 				
	Other (Specify)		 	<u> </u>		-						
Peripheral	Peripheral vessel		Р	ρ	P		Р	Р		BMDC	Note	
Vessei	Other (Specify)		 	 	-	1	 	 	 		2,3,4,5,7,8,9,1	

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D Imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominat, vascular
Note 7	Contrast agent imaging
Note 8	SleClear multi-view spatial compounding
Note 9	Tissue Equalization Technology
Note 10	Intracardiac imaging
Note 11	Dynamic TCE
	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)
(Dist)	Son Sign-Off) Prescription Use (Per 21 CFR 801.109)
Divie	ion of Reproductive, Abdominal and
	· ·
Radio	ological Devices
	· · · · · · · · · · · · · · · · · · ·
510(k) Number <u>Ko 90.76</u>
010	10 10011001

510(k) Number (if known):

Device Name:

EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	tion	Mode	e of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic						-				
	Fetal		ρ	Ρ	Ρ		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdomina!			ļ			}				
	Intra-operative (Note 6)		, **			<u> </u>					
	Intra-operative (Neuro)	,									
·	Laparoscopic										
Fetal	Pediatric					1					
imaging & Other	SmallOrgan (Note 1)		Р	Р	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephatic										
	Trans-rectal	-	Р	Ъ	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	1						ļ	,		
	Musculo-skel. (Superfic)										
	Intra-vascular								ļ		
· .	Other (Specify)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric										* L .s
	Intra-vascular (Cardiac)				-				·		****.
	Trans-esophagnal. (Cartiac)	•	1. 1.				-		74.3		
	kntra-camilac						ar da semilia				
	Other (Specify)	17.7			TES ICE KIDA		100000		4,		11 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Peripheral	Peripheral vessel										
Vessel	Other (Specify)										

N = new Indication; P = previously cleared by K080760

Intracardiac Imaging

Note 1	For example: breast, testes, thyrold, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SleScape panoramic imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SieClear multi-view spatial compounding
Note 9	Tissue Equalization Technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Note 10

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number _____ Co 90276

510(k) Number (if known):

Device Name:

L13F5 3D/4D Mechanical Wobbler Linear Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ation	Mode	e of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal		P	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominai		Ρ.	Р	Р		ρ	Р		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)	1					. é j	•			
	Intra-operative (Neuro)										
	Laparoscopic	i "					_				
Fetal	Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Imaging & Other	SmallOrgan (Note 1)		Р	Р.	è		Р	Р		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	Р	Р.	1	Р	Р	İ	BMDC	Note 2,3,4,5,7,8,9
,	Adult Cephalic	一				1			<u> </u>		
	Trans-rectai	İ						l			
	Trans-vaginal					1		, ,			
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	l	P	P	P		Р	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		Р	Р	Р		, Р	Р	,	BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular								1		
	Other (Specify)					ļ	,				
	Cardiac Adult					1		ŀ	}		
Cardiac	Cardiac Pediatric		1								
r	Intra-vascular (Cardiac)									1	Sequents.
	Trans-esophageal (Cardiac)	-					-				
	Intra-cardice	J.Y.					Recommendad to			Harayan ay managan a san na san a	
	Other (Specify)					AND THE REAL PROPERTY.	Post (manuscript)	Composition and the second	-		
Peripheras:	Peripheral vessel	1	*P	12	• 6		v ##	· (p.)	2152	BMDC/	Note 2,3,4,5,7,8,
Vessel	Other (Specify)	1	12]		*		-		•

N = new indication; P = previously cleared by K080760

Intracardiac imaging Dynamic TCE

Note 1	For example: breast, testes, thyrold, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Nate 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SieClear multi-view spatial compounding
Note 9	Tissue Equalization Technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Note 10

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number <u>Ko 902.76</u>

4

510(k) Number (if known):

Device Name:

VF8-3 Linear Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Fetal Finaging & Other	Specific (Tracks11& 3) Ophthalmic Fetal Abdominal Intra-operative (Noto 6) Intra-operative (Neuro) Laparoscopic Pediatric	A	P P	M P P	PWD P	CWD	Color Doppler P	Amplitude Dopplar	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Fetal F Imaging & Other	Fetal Abdominal Intra-operative (Note 6) Intra-operative (Neuro) Laparoscopic			P	·		P	P			
Fetal F Imaging S & Other	Abdominal Intra-operative (Noto 5) Intra-operative (Neuro) Laparoscopic			P	·		Р	Þ			
Fetal F Imaging & Other ()	Intra-operative (Note 6) Intra-operative (Neuro) Laparoscopic		Р		Р	1		. 「		BMDC	Note 2,3,4,5,7,8,9,11
Fetal F Imaging S & Other ()	(Note 5) Intra-operative (Neuro) Laparoscopic		- <u>- </u>				Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Fetal F Imaging S & Other ()	(Neuro) Laparoscopic		""		•	- 1 - 1 - 1	De la la la la la la la la la la la la la		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
Fetal F Imaging S & Other ((
Imaging S & Other (Pediatric										
& Other (Р	Р	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
<u></u>	SmallOrgan (Note 1)		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
_	Neonatal Cephalic		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
. L'	Trans-rectal										1
7	Trans-vaginal										
	Trans-urethral									·	
(Trans-esoph. (non-Card.)										
(Musculo-skel. (Convent.)		Р	Р	P		P ·	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)	-	Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular								1		
	Other (Specify)										
(Cardiac Adult			-			1				Note 12
Cardiac (Cardiac Pediatric							1			
(Intra-vascular (Cardiac)										
1.0	Trans-esophageal (Cardiac)					1811				<u> </u>	
	Intra-cardize Other (Specify)). 			<u> </u>		<u></u>	 	3 5	<u> </u>
	Peripheral vessel		P	Р	Р	1			+		
· ·	Other (Specify)		1			1	l P	l P	1	BMDC	Note 2,3,4,5,7,8,9,11 <u>,12</u>

N = new indication; P = previously cleared by K080760

lote.1	For example: breast, testes, thyroid, penis, prostate, etc.
lote 2	Ensemble tissue harmonic imaging
lote 3	3D Imaging
lote 4	B&W SieScape panoramic imaging
lote 5	Power SieScape panoramic imaging
lote 6	For example: abdominal, vascutar
lote 7	Contrast agent imaging
lote 8	SieClear multi-view spatial compounding
lote 9	Tissue Equalization Technology
lote 10	Intracardiac imaging
Jote 11	Dwamb TCF

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Division of Reproductive, Abdominal and	

Radiological Devices

510(k) Number <u>L090276</u>

510(k) Number (if known):

Device Name:

P5-1 Phased Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ition	Mode	of Ope	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic									·	
	Fetal		Р	Р	Ρ	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal 💉 🛴		P.	p.	P	Р	Р	, р		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)						y 1, 24 = .	1			
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric		Þ	Ρ	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)										
	Neonatal Cephalic		P	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		Р	Р	, Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal				·						
	Trans-vaginal			<u></u>		<u> </u>					
	Trans-urethral			<u> </u>	1						
	Trans-esoph. (non-Card.)									·	
	Musculo-skel. (Convent.)	٠.		ľ			1				:
	Musculo-skel. (Superfic)										
	Intra-vascular		1								
	Other (Specify)										,
	Cardiac Adult		Р	Р	P	Р	. Р	Р		BMDC	Note 2,3,4,5,7,8,9,1
Cardiac	Cardiac Pediatric	j	P	Р	. Р	Р	Р	Р		BMDC	Note 2,3,4.5,7,8,9,1
signi Ngjara is	intervisoriar (Curcien)	-	1					1		1	
	Trans-esophageat (Cardiac)								:		
	Intra-cardiac					1					
	Other (Specify)										
Peripheral	Peripheral vessel	Π	ρ	ρ	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9,
Vessel	Other (Specify)	1	 	†	1	† · · · · · · · ·		 	1	 	

Note 1	For example: he	ast testes thum	id oenis omstate etc

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Concurrence of CDRH, Office of Device Evaluation (ODE) (Division Sign-Off) escription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number _

KO 90276

Note 2 Ensemble tissue harmonic imaging

³⁰ imaging 8&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

For example: abdominal, vascular Note 6 Note 7

Contrast agent imaging
SieClear multi-view spatial compounding
Tissue Equalization Technology
Intracardiac imaging
Dynamic TCE Note 8

Note 9

Note 10 Note 11

510(k) Number (if known):

Device Name:

C6-2 Convex Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applica	ıtion	Mode	of Op	eration							
Other (Track1 Only)	Specific (Tracks1l& 3)	А	8	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										•
	Fetal		Þ	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Nots 6)	7,4		•			, , , , , , , , , , , , , , , , , , ,				
	Intra-operative (Neuro)		-								
	Laparoscopic										•
Fetal	Pediatric		Р.	Þ	P		Р	P		BMDC	Note 2,3,4,5,7,8,9,11
Imaging & Other	SmallOrgan (Note 1)							·			
	Neonatal Cephalic										
	Adult Cephalic			·			<u> </u>		· · · · · · · · · · · · · · · · · · ·		···
	Trans-rectal		1	L							
	Trans-vaginal										
•	Trans-urethral	<u> </u>				<u> </u>	<u> </u>				
	Trans-esoph. (non-Card.)					ļ		1			
	Musculo-skel. (Convent.)		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skeL (Superfic)					,					
	Intra-vascular	_	<u> </u>	<u> </u>	ļ					1	
	Other (Specify)										
	Cardiac Adult		P	P	P		Ρ	Р		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Pediatric		P	P	• Р		Р	Р	•	BMDC	Note 2,3,4,5,7,8,9,11
Same Services	Intra-vascular (Cardiac)			ļ		protest and a service of	to on point 5 in gamente in professionale				
4.4	Trans-esophageal (Cardiac)		ļ ,		[1	Treatment of the second				
	inira-cardiac	70. 1	1. :	<u> </u>	ene arweni Sen		· · · · · · · · · · · · · · · · · · ·		1 10	.	
• .	Other (Specify)										
Peripheral	Peripheral vessel		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify) ation; P = previously cla	``									

NOTE 1	r or example: preast, testes, triyroto, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example; abdominal, vascular
Aloto 7	Contract agent Impeles

Note 7 Contrast agent Imaging
Note 8 SieClear multi-view spatial compounding
Note 9 Tissue Equalization Technology

Note 9 Tissue Equalization Technology
Note 10 Intracardiac imaging
Note 11 Dynamic TCE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

510(k) Number (if known):

Device Name:

SoundStar 10F Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
	Fetal .									1	
	Abdominal					,					ź
	Intra-operative (Note 6)										· .
	Intra-operative (Nauro)										
	Laparoscopic										
Fetal	Pediatric										
tmaging & Other	SmallOrgan (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal							_			
	Trans-vaginal			<u> </u>							
	Trans-urethral Trans-esoph.						·				
	(non-Card.)		ļ								
	Musculo-skel. (Canvent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular		Р	P	P	P	P	Р		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
	Cardiac Adult		P	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8,9,10,11
Cardiac	Cardiac Pediatric		P	Р	P	P	P	Р		BMDC	Note 2,3,7,8,9,10,11
	intra-vascular (Cardiac)		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8,9,10,11
1.24	Trans-esophageal			ep. cox	ر المارية						
	Intra-cardiac		P	ļ-		P	- P	5		BMDC.	Note 2,3,7,8,9,10,11
	Other (Specify)					,					
Peripheral	Peripheral vessel		1	<u> </u>							
Vessel	Other (Specify)	L	<u> </u>	<u> </u>	<u> </u>	1					

N = new indication; P = previously cleared by K080760;

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic Imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominal, vascular

Note 7 Contrast agent imaging SieClear multi-view spatial compounding Tissue Equalization Technology

Note 10

Intracardiac imaging Dynamic TCE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign Off)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

510(k) Number (if known):

Device Name:

P9-4 Phased Array Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion	Mode	of Ope	eration			,		•		
Other (Track1 Only)	Specific (Tracks1l& 3)	A	В	М	PWD	CWD	Calor Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										· ·
7. T.	Fetal		N	N	N	N	N	N		8MDC	Note 2,3,4,5,7,8,9,11
	Abdominal		N	N	N	N	N	N		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)					447.7		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
-	Intra-uperative (Neuro)		Z	Z	N	-, k	'N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
Fetal	Pediatric		N	N	N	. N	N	N		BMDC	Note 2,3,4,5,7,8,9, <u>11</u>
Imaging & Other	SmallOrgan (Note 1)		И	N	N	N	N	N		вмос	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic	1	N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal				_					1	.:
	Trans-veginal	<u> </u>							ļ	<u> </u>	
	Trans-urethral Trans-esoph.	<u> </u>	ļ	<u> </u>			ļ		<u> </u>	 	
	(non-Card.)		1			ļ				ł	
, .	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)				_						
	Intra-vascular							İ	1		
	Other (Specify)										
	Cardiac Adult		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Pediatric		, N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)				, ,,						4505
ga Taguna ar e Taguna ar kulin i	Tress escenageal /		13.0		-	,				*	
and the state of	Intra-cardiac		J			1	1		4.5	7	
	Other (Cardiac Neonatal)		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9,1
Peripheral	Peripheral vessel		N	N	N	N	N	N		, BMDC	Note 2,3,4,5,7,8,9,1
Vessel	Other (Specify)	1			<u> </u>						

N = new indication; P = previously cleared by FDA

Note 1	For example: breast,	testes, thyroid, p	penis, prostate, etc.

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 		 	-	-

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Concurrence of CDRH, Office of Device Evaluation (CDE) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

KOgozza 510(k) Number

Ensemble tissue harmonic imaging

³D imaging B&W SieScape panoramic imaging Note 4. Note 5 Power SieScape panoramic imaging Note 6 For example: abdominal, vascular

Note 7

Contrast agent imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 8 Note 9 Note 10 Note 11

intracardiac imaging Dynamic TCE